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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/18/2003

*CS*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/462,517

Applicant(s)

ZUKER ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 16, 18 and 20-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Applicant's election with traverse of Invention V, claims 14, 15, and new Claims 41-45, as drawn to the InaD protein having SEQ ID NO: 1 in Paper No. 20 filed December 19, 2002 is acknowledged. The traversal is on the ground(s) that Inventions V and VI recite methods for identifying modulators of signal transduction that include the same structures and polynucleotides. The difference between independent claims 14 and 16 is in the polynucleotides. In Claim 16 the polynucleotides permits increased expression of the transducisome and is not limited to encoding the transducisome. Therefore, the polynucleotides are different, and the search and issues of one is not the same as the other. In Claim 18, which depends from Claim 16, the second cell lacks a signal transduction protein, thus again the search and issues differ between the claimed inventions. Therefore, these Inventions differ in the cells used in the methods and are patentably distinct.

Applicants further request that the Examiner acknowledge that the election of SEQ ID NO: 1 is a species election from a genus of transducisomes. The restriction was clearly written and stated that the election of a sequence is not considered to be a species election. Further, Applicants' broad claim has been anticipated as set forth below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 16-18, and 20-41 have been withdrawn by the Examiner because these claims are drawn to non-elected inventions. Claims 14, 15, and 41-45 are currently under examination.

Priority is granted to SN 60/052588, filed on July 15, 1997.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 41-45 recite acronyms, said acronyms should be spelled out to prevent confusion as to their meaning.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 15, 41, and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Shieh et al. (1995; Neuron 14:201-210). Shieh et al. teach that phototransduction is a model system for G-protein coupled signal transduction. In the visual cascade, light activates rhodopsin, which interacts with heterotrimeric GTP-binding protein (transducin) to catalyze the exchange of GDP to GTP at the  $G\alpha$  subunit. The GTP-bound form of transducin  $\alpha$  subunit, in turn, activates cyclic GMP (cGMP) phosphodiesterase that hydrolyzes cytosolic cGMP to GMP. The reduction of cGMP leads to closure of the cGMP-gated cation channels and hyperpolarization of photoreceptor cells.

Specifically, in Figure 6 with reference to the section entitled "The abnormal deactivation kinetics in *InaD* are dependent on extracellular calcium" on page 206, Shieh et al. compared the effects of calcium on wild type photoreceptors comprising the normal *InaD* or p59B gene product (see pages 202-204) and the *InaD*<sup>p215</sup> comprising missense mutation Met442Lys in response to light induced currents as assessed by whole cell patch clamp recordings.

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Therefore, Shieh et al. teach a method for identifying modulators of signal transduction by contacting a first cell such as a photoreceptor cell was contacted with a test chemical which is calcium, wherein the cell comprises more than one signal transport protein such as components of the G-protein couple receptor (GPCR) signal transduction pathway as noted by Shieh et al. teach that phototransduction is a model system for G-protein coupled signal transduction, wherein the cell comprises a polynucleotides encoding a transducisome, which is defined in the specification as a protein comprising a PDZ domain, or wild-type InaD, which binds to signal proteins to permit signal transduction (Claim 14a). The signal transduction was activated by light induced currents (Claim 14b). The signal transduction was detected by whole cell patch clamp recordings (Claim 14c).

A second cell such as a photoreceptor cell was contacted with a test chemical which is calcium, wherein the cell comprises more than one signal transport protein such as components of the G-protein couple receptor (GPCR) signal transduction pathway as noted by Shieh et al. teach that phototransduction is a model system for G-protein coupled signal transduction, wherein the cell comprises a polynucleotides encoding a mutant or defective transducisome, which is defined in the specification as a protein comprising a PDZ domain having a mutation in the PDZ domain, or InaD<sup>P215</sup> having mutation Met442Lys, which fails to bind to signal proteins to permit signal transduction or fails to be expressed (Claim 14d). The signal transduction was activated by light induced currents (Claim 14e). The signal transduction was detected by whole cell patch clamp recordings (Claim 14f). The signal transduction was compared between the wild type InaD and the mutant InaD (Claim 14g).

The first and the second cell were photoreceptor cells and therefore the same, and the second cell expressed InaD having a mutation in the PDZ domain which fails to bind to signal proteins to permit signal transduction (Claim 15).

The transducisome protein is InaD (Claim 41).

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Because the photoreceptor cells comprise a GPCR and associated signal transduction pathways, the selection of signal transduction proteins in Claim 43 are found in photoreceptor cells. Additionally, Shieh et al. at Fig 2A and corresponding legend teach that InaD is phosphorylated by protein kinase C, camp-cGMP-dependent protein kinases, and tyrosine kinases. Thus, InaD binds these signal transduction proteins. Further, Shieh et al. expressly point out at page 201, col. 2, that invertebrates, such as *Drosophila*, comprise phospholipase C, protein kinase C, and transient receptor potential (TRP) protein (Claim 44).

Claim 41 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER